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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,184	07/30/2003	Naina Sachdev	Sa-1	9221

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EAST BRUNSWICK, NJ 08816

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,184

Applicant(s)

SACHDEV, NAINA

Examiner

Frank I. Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-5, 7,8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nagai et al. (US Pat. 4,446,149)

Nagai et al. expressly discloses a composition containing 3, 5 or 10% L-carnosine in an aqueous solution falling within the scope of applicant's claims. (Column 4, lines 44-47). The aqueous solutions will have a pH of 8-8.5(Column 2, lines 50,51). The solution contains water which would at the least fall under the categories of cell stimulant or growth promoting and bio-activating agent.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same

exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 1,5,7,8 are rejected under 35 U.S.C. 102(a or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over *Boussouira et al.* (US Pat. 6,358,514).

Boussouira et al. expressly discloses a composition containing 0.1% carnosine or carnosine derivative, all-trans retinol, ethanol and water at a pH of 8.2 falling within the scope of applicant's claims (column 10, lines 30-53).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Examiner has considered Applicant's declaration, however, said declaration does not indicate that "about 0.5%" excludes 0.1% of carnosine. "[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if one of them is in the prior art." *Titanium Metals Corp. v. Banner*, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 133 USPQ 275, 280 (CCPA 1962)). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.); *In re Geisler*, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim

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reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that suitable protection' is provided if the protective layer is about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range."). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.).

Claims 1,3, 5,7,8 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bagrov et al. (US Pat. 6,629,970).

Bagrov et al. expressly discloses a composition containing 0.1-20 mg/ml carnosine, complex of glycosaminoglycans with at least one metal of calcium, magnesium, zinc, aluminum, copper, iron or manganese with a pH of 7.2-7.6 (Column 1, lines 53-68, Column 2, lines 1-12, Claim 1, Claim 3) falling within the scope of applicant's claims (column 10, lines 30-53).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Examiner has duly considered Applicant's arguments, however, Applicant has not shown a "pH of about 8" excludes a pH of 7.6 or even 7.2. See discussion above.

Claims 1, 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grigg (US 2003/0118525) in view of Boussouira et al. (US Pat. 6,358,514).

Grigg discloses a composition containing carnosine, compounds related to carnosine, acylcarnosines, such as N-acetyl carnosine, and esters of acylcarnosines, preferable in combination with other antioxidants such as vitamin E, lipoic acid, cysteine, cysteine derivatives, folic acid, phytic acid, citric acid, lactic acid, zinc oxide, ubiquinone, in the form of a gel, cream or other cosmetic formulations (paragraphs 0025-0031, 0036-0046) A cosmetic cream is disclosed containing 0.1% or 1.00 % carnosine or 0.1% acetylcarnosine (Paragraphs 0056-0057). It is disclosed that carnosine and N-acetyl carnosine are effective in blocking erythema and oedema induced by exposure of the skin to solar radiation (Paragraphs 0013-0024).

Boussouira et al. disclose a composition having a pH of preferably greater than equal to 7 and less than or equal to 10, for example 7.5, 8.0, 8.5, 9.0, 9.5, a carnosine derivative (0.001 to 20% by weight, advantageously from 0.05 to 10%, including 0.5, 1,2,5,15, and 18% by weight) and retinoid which is applied to the skin or face and can be in the form of a lotion, gel, w/o or o/w emulsion, care cream, milk, tonic, cleansing and/or make-up-removing product, erasing product, exfoliant, sunscreen or foundation (Column 4, lines 33-68, Columns 4-9, Column10, lines 1-7) A example is disclosed containing carnosine or carnosine derivative, all-trans retinol, ethanol and water at a pH of 8.2 which stabilizes retinol versus retinol alone (column 10, lines 15-63, Column 11, lines 1-20). It is disclosed that addition of carnosine derivative to the retinoid increase the stability of the retinoid (Column 11, lines 1-20).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the use of a carnosine derivative in an amount of about 1.5% to about 30%, or 10% to 20% by weight or the use of N-acetyl carnosine. However, the prior art amply suggests the same as the prior art disclose the use of 0.001 to 20% by weight, advantageously from 0.05 to 10%, including 0.5, 1, 2, 5, 15, and 18% by weight of the carnosine derivative. As such, it would have been well within the of and one of ordinary skill in the art would have expected that the use of varying amounts of carnosine derivative, including amounts falling within the claimed ranges, or the use of N-acetyl carnosine would be effective in stabilizing the retinoid contained in the prior art composition.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Contrary to Applicant's arguments, Boussuira does not disclose that carnosine failed to stabilize retinol nor does Applicant's declaration show that Boussuira was unsuccessful. In fact, versus retinol alone, carnosine at an amount of 0.1% was able to partially stabilize retinol. As such, one of ordinary skill in the art would expect that higher amounts of carnosine would be effective in stabilizing more retinol. Applicant's declaration shows nothing more than would be expected from the disclosure in Boussuira. Applicant's citation to Yu et al. does not overcome the rejection herein as the claims are not rejected over Yu et al.. As such, any affidavit purporting to overcome Yu et al. cannot overcome the rejection herein. Contrary to Applicant's arguments, there is specific guidance to use a pH falling within the claimed ranges, as indicated above.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been taught by the teachings of the cited reference.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.


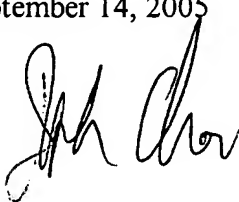
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

September 14, 2005



John Pak
Primary Examiner
Group 1600